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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	13704/2	9876

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,703	DOYLE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-7-06 has been entered. Claims 51-64 are pending and under examination.

Rejections Withdrawn

Claims 8, 9, 12, 39 and 41-43 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the submission of new the claims.

Claims 1, 4, 7, 8, 9, 12, 39 and 41-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the submission of new the claims.

Rejections Maintained

Claims 51-64 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00) is maintained for reasons made of record in the Office Actions Mailed 9-27-04 and 6-9-05 for claims 1, 4, 7, 8, 9, 12, 39 and 41-50.

Applicants' arguments have again been carefully considered but are not persuasive. Applicant's method is a single step "screening for an increase in the levels of SP-B in a body fluid of the mammal relative to a normal reference level". Applicants submit that

Doyle et al do not show any significant difference in SP-B levels between the control group and the other disease group and as such do not meet the limitation of the claim "screening for an increase" in the indicated patient population of the preambles of either claim 51 or 57. This is not persuasive the method step of "screening for an increase" is seen to encompass testing of those individuals that do not have an increase. "Screening" for something is the detection of the presence or absence and as such the measurement in normal individuals and individuals with other disease and on ventilators is screening for an increase in the normal patient populations. Normal and the other tested patients are asymptomatic to lung damage, alveolo-capillary membrane damage or at a time period wherein the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures. Theses patient populations clearly meet the preamble and encompass testing normal or other control individuals not placable in any particular disease group. The testing of a control or other disease is a screen for an increase in an individual. The other disease is compared to normal controls. Therefore, screening the normal and other disease controls of Doyle et al do in fact meet the limitation of "screening for an increase" and the specifically recited patient populations of the preambles of claims 51 and 57. Doyle et al specifically appreciated that "We concluded that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of lung injury ..." (page 152, see first line of Conclusions). As such, the art specifically teaches that the levels of surfactant proteins specifically correlate with the degree of injury (i.e. lung damage) in a mammal. In contrast to Applicants' arguments, Doyle et al does meet the limitations of the claims as set forth *supra*. Additionally, it is noted that the patient populations of the art are the same patient populations tested and disclosed in the specification for support for the now claimed invention (see Example 6, pages 24-26).

Doyle et al teach measuring SpA and SpB to screening for increases in a variety of patients including ventilated patients with no evidence of cardiorespiratory disease and

screening of normal individuals (see page 152, Table 1) in sera (i.e. the instant blood). Doyle et al teach that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of the lung injury (i.e. the instantly claimed lung damage). Doyle et al teach that when taken individually, daily changes in lung function were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/A. (see page 152, first full line of text). Doyle et al teaches the claimed invention.

The rejection is maintained.

Claims 51-64 also stand rejected under 35 U.S.C. 103(a) as being unpatentable over Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996; reference A11 on PTOL-1449 of 6-6-00 in view of Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00) and Abe et al (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6-6-00) for reasons made of record in the Office Action mailed 6-9-05 for claims 8, 9, 12, 39 and 44-50.

It is noted that the preamble of the claims is interpreted by the teaching of the specification to still encompass read on "early stage" as defined in the specification and chronic disease but currently asymptomatic patients. Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that since Doyle et al fails, so does the combination based on Doyle. This is not persuasive, Doyle et al does not fail for reasons set forth above. Applicants generically argue that the references must suggest all the claim limitations, however fail to point out which limitations are not met by the prior art. Applicants generically argue that there is no motivation to combine the references. This is not persuasive, motivation was specifically articulated in the rejection. The combination of cited references indicate that SP-B would have been more sensitive because it enters the circulation more readily than SP-A. Further, the combination

explicitly indicate that SP-B reflects the severity of the lung disease and fluctuates with disease activity and daily changes in lung function. As previously set forth it would have been obvious to screen for increases as compared to normal to detect lung disease and changes in lung function in any individual at any point in the disease process (quiescent or exacerbations).

The rejection is maintained for reasons made of record.

Status of the Claims

All claims stand rejected.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Acting Supervisory Examiner Mark Navarro can be reached on 571-272-0861.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645